DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2015

Cardinal Health 200, LLC.
Ms. Lavenia Ford
Manager, Regulatory Affairs
1500 Waukegan Road
Waukegan, IL 60685

Re: K150151
Trade/Device Name: SmartGown™ Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA,
Dated: April 23, 2015
Received: April 24, 2015

Dear Ms. Ford,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1500 Waukegan Road
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510(k) SUMMARY
SmartGown™ surgical gown

Manufacturer:	Cardinal Health 200, LLC 1500 Waukegan Road Waukegan, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road Waukegan, IL 60085
Telephone Number:	(847) 887-3323
Fax Number:	(847) 785-2461
Date summary Prepared:	April 21, 2015
Trade Name:	SmartGown™ surgical gown
Regulation Number/Device Class:	Class II per 21 CFR § 878.4040
Regulation Name:	Surgical Apparel
Common Name:	Surgical Gown
Product Code:	FYA
Predicate Device:	K012984 –Cardinal Health SmartGown™

Description

The Cardinal Health SmartGown™ surgical gowns are identified by Regulation 21 CFR 878.4040 with product code FYA.

The Cardinal Health SmartGown™ surgical gowns are constructed of a multi-layer construction of a nonwoven outer layer, breathable film core and a nonwoven inner layer and have been tested according to AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health care Facilities. The Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device that will be provided in a variety of sterile and non-sterile packaging configurations. This submission covers 12 models of Cardinal Health SmartGown surgical gowns, see **Table 1** below.

Indications for Use

Cardinal Health SmartGown™ surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device provided sterile and non-sterile.

This submission covers 12 models of Cardinal Health SmartGown™ surgical gown, see **Table 1** below. Each model is a multi-layer construction of a nonwoven outer layer, breathable film core and a nonwoven inner layer, and has been tested according to AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities.

Table 1: Product Description and Catalog Number

Catalog #					
Sterile	**Non-sterile**				
Single	Bulk	Hospital	Bulk Small Qty	**Model Description**	**Model Size**
89013	N/A	N/A	N/A	SmartGown™ surgical gown, Set-in sleeve	X-Small
89005	89005N	N/A	N/A	SmartGown™ surgical gown, Set-in sleeve	Small/Medium
89015	89015N	N/A	890015N	SmartGown™ surgical gown, Set-in sleeve	Large
89045	89045N	N/A	890045N	SmartGown™ surgical gown, Set-in sleeve	X-Large
89075	89075N	K89075N	N/A	SmartGown™ surgical gown, Set-in sleeve	XX-Large
39015	39015N	K39015N	N/A	SmartGown™ surgical gown, Raglan sleeve	Large
39045	39045N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	X-Large
39049	39049N	K39049N	N/A	SmartGown™ surgical gown, Raglan sleeve	X-Large, X-Long
39075	39075N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XX-Large
39079	39079N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XX-Large, X-Long
39099	39099N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XXX-Large, X-Long
32474	32474N	K32474N	324740N	SmartGown™ surgical gown (specialty), Raglan sleeve	X-Large, X-Long, A-Line

The Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device provided in a variety of sterile and non-sterile packaging configurations. Bulk non-sterile Cardinal Health SmartGown™ surgical gowns provided to convenience kit packers.

Non-sterile Cardinal Health SmartGown™ surgical gowns will include EO sterilization parameters on labeling as follows:

- EO Concentration: 690 mg/L
- Temperature: 130 +/- 10°F
- Exposure Time: 150 minutes
- Humidity: 50 +/- 5%
- Aeration Time: 18 hours

Device and Predicate Device Technical Characteristics

The proposed Cardinal Health SmartGown™ surgical gowns are primarily construction of nonwoven and nonwoven laminates (**see Table 3**).

Table 3: Proposed Cardinal Health SmartGown™ surgical gown description

Design	Body and front tie attachment AAMI PB70 Critical Zone	Sleeve and sleeve seam AAMI PB70 Critical Zone	Back Panel AAMI PB70 Non-Critical Zone	Codes
Set-in sleeve	SMS / Film / SMS Meets: ASTM F1671 AAMI PB70 Level 4	SB / Film / SB Meets: ASTM F1671 AAMI PB70 Level 4	SMS / Film / SMS Meets: ASTM F1671 AAMI PB70 Level 4	**89013** **89005** **89015** **89045** **89075** **89005N** **89015N** **89045N** **89075N** **890015N** **890045N** **K89075N**
Raglan sleeve	SMS / Film / SMS Meets: ASTM F1671 AAMI PB70 Level 4	SB / Film / SB Meets: ASTM F1671 AAMI PB70 Level 4	SMS / Film / SMS Meets: ASTM F1671 AAMI PB70 Level 4	**39015** **39045** **39049** **39075** **39079** **39099** **39015N** **39045N** **39049N** **39075N** **39079N** **39099N** **K39015N** **K39049N**
Raglan sleeve, Aline	SMS / Film / SMS Meets: ASTM F1671 AAMI PB70 Level 4	SB / Film / SB Meets: ASTM F1671 AAMI PB70 Level 4	SMS Meets: AATCC 42 ≤ 1.0g AATCC 127 ≥ 50cm AAMI PB70 Level 3	**32474** **32474N** **324740N** **K32474N**

The Cardinal Health SmartGown™ surgical gowns consist of zones; body, sleeve and back panel. The body front and lower sleeve are critical per AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health care Facilities, refer to **Table 3** below.

The Cardinal Health SmartGown™ surgical gowns are substantially equivalent to the predicate SmartGown surgical gown with regards to claims, safety and effectiveness, design, technology, and intended use. See **Table 4** below.

The proposed Cardinal Health SmartGown™ surgical gown body and sleeve materials are a laminated structure consisting of an outer layer of polyolefin nonwoven, laminated to a monolithic breathable barrier film, which is laminated to an inner layer of polyolefin nonwoven. The body material is constructed of an outer layer of SMS polyolefin nonwoven, laminated to a monolithic breathable barrier film, which is laminated to an inner layer of SMS polyolefin nonwoven. The gown sleeves are constructed of an outer layer of SB polyolefin nonwoven, laminated to a monolithic barrier film, which is laminated to an inner layer of SB polyolefin nonwoven.

The proposed Cardinal Health SmartGown™ surgical gown (specialty) non-critical zone body back panels are constructed of polyolefin SMS nonwoven fabric. The surgical gown back panels are not a critical zone per AAMI PB70:2012.

Testing was performed according to the *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*, issued on August 1, 1993 and AAMI PB70: June 21, 2012, *Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.* All results of testing met ASTM F1671/F1671M-13, and meets AAMI PB70:2012 Level 4 requirements.

Table 4: Side by Side Comparison of Predicate device and Proposed Cardinal Health SmartGown™ surgical gown

Element of Comparison	Predicate Cardinal Health SmartGown™ surgical gown	Proposed Cardinal Health SmartGown™ surgical gown

Intended Use		The predicate Cardinal Health SmartGown™ surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The predicate Cardinal Health SmartGown™ surgical gown is intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The predicate Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device, provided sterile and non-sterile.	The proposed Cardinal Health SmartGown™ surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The proposed Cardinal Health SmartGown™ surgical gown is intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The proposed Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device, provided sterile and non-sterile.
Material Composition		Predicate Cardinal Health SmartGown™ surgical gown critical zones are a multi-layer construction of nonwoven outer (polyolefin spunmelt), monolithic film core (copolyester), nonwoven inner (carded polyester).	Proposed Cardinal Health SmartGown™ surgical gown body critical zone is a multi-layer construction of nonwoven outer (polyolefin SMS), monolithic film core (copolyester), nonwoven inner (polyolefin SMS). Proposed Cardinal Health SmartGown™ surgical gown sleeves critical zone are multi-layer construction of nonwoven outer (SB), monolithic film core, nonwoven inner (SB).
Design Feature		Predicate Cardinal Health SmartGown™ surgical gown is provided with neck binding with hook and loop tabs, belt ties, removable transfer tab accessory, and cuffs	Proposed Cardinal Health SmartGown™ surgical gown is provided with neck binding with hook and loop tabs, belt ties, removable transfer tab accessory, and cuffs. Proposed Cardinal Health SmartGown™ surgical gown (specialty) non critical zone back panels are polyolefin SMS nonwoven fabric.
Element of Comparison		**Predicate Cardinal Health SmartGown™ surgical gown**	**Proposed Cardinal Health SmartGown™ surgical gown**	
		Performance (+/- 3 Sigma)	*Test Results Mean (min / max)*	*Material Specification*
Physical Properties (Critical Zone per	ASTM D3776 Basis weight (gsm)	67.81 – 88.15	Body: 52.1 (51.3 / 53.1) Sleeve: 69.6 (69.0 / 70.3)	Body: 50.9 Mean min Sleeve: 65.1 Mean min
	ASTM D5034 Grab tensile MD (lb)	25.9 – 39.7	Body: 26.3 (23.6 / 29.3) Sleeve: 30.0 (27.2 / 36.0)	N/A *

AAMI PB70:2012)	ASTM D5034 Grab tensile CD (lb)	14.9 – 20.3	Body: 17.8 (15.9 / 20.0) Sleeve: 23.9 (21.9 / 26.0)	Body: 14.4 Mean min Sleeve: 18.0 Mean min
	ASTM D5733 Trap Tear Peak MD (lb)	Performance values not available in predicate 510(k) submission	Body: 5.6 (4.4 / 6.8) Sleeve: 7.7 (6.0 / 9.9)	Body: 4.0 Mean min ** Sleeve: 5.4 Mean min **
	ASTM D5733 Trap Tear Peak CD (lb)	Performance values not available in predicate 510(k) submission	Body: 8.9 (6.9 / 10.4) Sleeve: 10.7 (9.0 / 12.5)	N/A **
	ASTM D774 Mullen burst (psi)	32.1 – 59.1	Body: 34.3 (31.2 / 37.9) Sleeve: 45.1 (39.5 / 49.4)	Body: 30.0 Mean min Sleeve: 36.9 Mean min
	ASTM E96 WVTR, upright cup @ 23°C, 50%RH (g/m^2/24hours)	640 – 1007	Body: 822 (752 / 866) Sleeve: 764 (724 / 814)	Body: 740 Mean min Sleeve: 708 Mean min
	ASTM E96 WVTR, upright cup @ 27°C, 50%RH (g/m^2/24hours)	820 – 1332	Body: 983 (951 / 1022) Sleeve: 918 (876 / 983)	Body: 931 Mean min Sleeve: 833 Mean min
	ASTM E96 WVTR, upright cup @ 32°C, 50%RH (g/m^2/24hours)	1005 – 1707	Body: 1439 (1323 / 1618) Sleeve: 1251 (1185 / 1426)	Body: 1191 Mean min Sleeve: 1117 Mean min
	(CPSC), Part 1610 Flammability	Class 1	Body: Class 1 Sleeve: Class 1	Body: Class 1 Sleeve: Class 1
	AAMI PB70 Barrier Performance Level	Performance standard not available at time of predicate submission.	Body: Level 4 Sleeve: Level 4	Body: Level 4 Sleeve: Level 4
Physical Properties (SMS Back panel Non-Critical Zone per AAMI PB70:2012)	ASTM D3776 Basis weight (gsm)	Performance values not available in predicate 510(k) submission	Back Panel: 34.6 (33.4/35.8)	Back Panel: 31.5 Mean min
	AATCC-42 Water Impact (g)	Performance values not available in predicate 510(k) submission	Back Panel: 0.12 (0.08/0.20)	Back Panel: 0.5 Mean max
	ASTM D5034 Grab tensile MD (lb)	Performance values not available in predicate 510(k) submission	Back Panel: 18.8 (15.8/21.5)	N/A *
	ASTM D5034 Grab tensile CD (lb)	Performance values not available in predicate 510(k) submission	Back Panel: 12.5 (9.2/14.8)	Back Panel: 10.0 Mean min
	ASTM D5733 Trap Tear Peak MD (lb)	Performance values not available in predicate 510(k) submission	Back Panel: 3.7 (2.8/5.1)	Back Panel: 3.0 Mean min
	ASTM D5733 Trap Tear Peak CD (lb)	Performance values not available in predicate 510(k) submission	Back Panel: 6.0 (4.8 / 7.8)	N/A **
	AATCC 127 Hydrostatic Head (cm)	Performance values not available in predicate 510(k) submission	Back Panel: 69.0 (50.7/78.7)	50 Mean min
	(CPSC), Part 1610 Flammability	Performance values not available in predicate 510(k) submission	Back Panel: Class 1	Class 1
			* MD Grab tensile not specified, CD Grab tensile is limiting specification value ** CD Trap tear not specified, MD Trap tear is limiting specification value	
Liquid Barrier Performance Classification Properties		Predicate device was tested according to ASTM F1671-97 in previous 510(k) submission K012984.	Device was tested in accordance with ASTM F1671/F1671M-13, and meets AAMI PB70:2012 Level 4	

		requirements.
Sterilization Modality	Ethylene Oxide	Ethylene Oxide
Biocompatibility	Pass ISO 10993-1	Pass ISO 10993-1

Table 4 highlights the equivalencies and comparison between proposed Cardinal Health SmartGown™ surgical gown and predicate Cardinal Health SmartGown™ surgical gown.

Final finished goods, that were twice EO sterilized (Cardinal Health SmartGown™ surgical gown), were tested. The products were tested in the critical zones of the body and sleeve to generate test data shown in Table 4 above, including back panels where noted. Test results establish that the product meets predetermined acceptance criteria of specifications for intended use, to demonstrate device is safe and effective, as noted in Table 4 above.

- **Mass Per Unit Area (Basis Weight) of Woven Fabric**

  ASTM D3776-09 Test Methods for Mass Per Unit Area (Weight) of Woven Fabric results were reported on the Body, Sleeve and Back Panel materials. This method was used to characterize the basis weight of each fabric. The basis weight test indicates how much a square meter of the fabric weighs. Each test specimen is cut to a specific size and the mass of the specimen is measured on a laboratory scale. The basis weight is calculated from that information. Results are reported in grams per square meter. The sample size used was n=32 and results were reported in mean, min and max.

- **Breaking Strength and Elongation of Textile Fabrics (Grab tensile)**

  ASTM D5034-09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) results were reported on the Body, Sleeve and Back Panel materials. This method was used to characterize the tensile strength of each fabric. The grab tensile test indicates the force a fabric can withstand before tearing when pulled in a given direction. The test was performed in both roll orientations; cross direction (CD) and machine direction (MD). The test specimen is placed in the clamps of a tensile testing machine. The test specimen is subjected to an increasing force as the jaws move apart at a specified constant rate. Results are reported as peak force values. Peak values reflect the maximum force the sample endured before the initiation of failure. Results are reported in pounds of force. The sample size used was n=32 and results were reported in mean, min and max.

- **Bursting Strength of Textile Fabrics (Mullen burst)**

ASTM D774/D774M-97 (2007) Standard Test Method for Bursting Strength of Textile Fabrics (Mullen Burst) results were reported on the Body and Sleeve materials. This method was used to characterize the burst strength of each fabric. The bursting strength test indicates how the fabric will resist puncture by a blunt object. Each fabric specimen is clamped over a flexible diaphragm. The diaphragm is expanded by pressure to the point of specimen rupture. The difference between the total pressure required to rupture the specimen and the pressure on the diaphragm at time of specimen burst with clamp released is reported as the Mullen burst strength. Results are reported in pounds per square inch. The sample size used was n=32 and results were reported in mean, min and max.

- **Water Vapor Transmission of Materials, Upright cup**

  ASTM E96/E96M-13 Standard Test method for Water Vapor Transmission of Materials, Upright cup (WVTR) results were reported on the Body and Sleeve materials. This method was used to characterize the water vapor transmission rate of each fabric over a range of temperatures at 50%RH (23°C, 27°C, 32°C). The water vapor transmission rate test specimen is affixed over a sample cup of water. The prepped sample cup is weighed at time 0. The prepped sample cup is then is heated to the target temperature, in chamber with constant %RH. The prepped sample cup is then measured at predetermined time points to measure the mass loss (water vapor transmission thru the sample). The water vapor transmission rate results are reported as mass of water per unit of area per period of time (g/m2/24 hours). The sample size used was n=32 and results were reported in mean, min and max.

- **Standard for the Flammability of Clothing Textiles**

  16 CFR Part 1610, Standard for the Flammability of Clothing Textiles, provides methods of testing the flammability of clothing and textiles intended to be used for clothing, and establishes three classes of flammability. The standard sets forth the requirements which textiles shall meet to be so classified. Class 1 is the best performing class. Textiles meeting these requirements are generally accepted by the trade as having no unusual burning characteristics. The flammability test indicates the inherent flammability classification of the surgical gown. Flammability results were reported on the Body, Sleeve and Back Panel materials. The sample size used was n=32 and results were reported as the Flammability Classification Level.

- **Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure (Trap tear)**

  ASTM D5733-99 Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure results were reported on the Back Panel material. This method

was used to characterize the tear strength of the material. The trapezoidal tear test indicates how the fabric will resist tearing around an existing hole or tear. The test was performed in both roll orientations; cross direction (CD) and machine direction (MD). A tear of specified size and orientation is initiated on the test specimen. The test specimen is placed in the clamps of a tensile testing machine. The test specimen is subjected to an increasing force as the jaws move apart at a specified constant rate. Results are reported as average trapezoidal tear strength, in pounds of force. The sample size used was n=32 and results were reported in mean, min and max.

- **Water Resistance: Impact Penetration Test**

  AATCC 42-2013 Water Resistance: Impact Penetration Test results were reported on the Back Panel material. This method was used to characterize the water resistance to impact penetration of the material. The impact penetration test measures the fabric's resistance to penetration by liquids, which is a key barrier property. The test specimen and a fluid blotter paper are cut to a predetermined size. The blotter is then weighed prior to testing. The test specimen and blotter are then clamped onto the test fixture (test specimen on top of blotter). A predetermined amount of water is allowed to spray on the sample from a fixed distance and spray head. The blotter is then weighed to determine the amount of water penetration thru the sample. The amount of liquid penetration is the final blotter weight less the initial blotter weight. The results are reported in grams. The sample size used was n=32 and results were reported in mean, min and max.

- **Water Resistance: Hydrostatic Pressure Test**

  AATCC 127:2013 Water Resistance: Hydrostatic Pressure Test results were reported on the Back Panel material. This method was used to characterize the resistance of a fabric to the penetration of water under hydrostatic pressure, which is a key barrier property. The test specimen is clamped the test chamber, which is filled with water to contact the sample. The water pressure is gradually increased, exerting greater pressure onto the fabric. The unexposed side of the fabric is observed for water droplets, signaling failure of the barrier feature of the test fabric. Eventually, leakage occurs, marking the end of the test. The greater water pressure, the more repellent the fabric. Results are reported in centimeters of water. The sample size used was n=32 and results were reported in mean, min and max.

- **Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood – Gown**

ASTM F1670-08, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood, evaluates the effectiveness of materials used in protective clothing for protecting the wearer against contact with body fluids that potentially contain blood-borne pathogens. This test method is intended to identify protective clothing material candidates for further testing according to a more rigorous procedure involving a surrogate for blood-borne pathogens. The test specimen is clamped onto the open face of pressure chamber of defined size, with a retaining ring around the outer circumference of the specimen. The pressure chamber is filled with synthetic blood. The specimen is exposed to the synthetic blood for a defined dwell period of time at ambient pressure. Then, chamber is pressurized, at a specified constant rate, to a maximum of 2 psi, for a defined period of time. The chamber is then allowed to revert to ambient pressure, and the specimen is exposed to the synthetic blood for a defined dwell period of time, to the conclusion of the test. A mesh screen may be used to support the specimen. Throughout the cycle, the reverse side of the fabric is observed for synthetic blood droplets, signaling failure of the barrier feature of the test fabric. If no droplets are observed thru the entire cycle, the sample passes. Results are reported as pass/fail. Procedure B was used, with a mesh screen to support the sample during testing. The sample size used was n=32 and results were reported as pass/fail.

- **Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System – Gown**

  ASTM F1671/F1671M-13, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System, evaluates the effectiveness of materials used in protective clothing for protecting the wearer against contact with blood-borne pathogens using a surrogate microbe suspended in a body fluid simulant under conditions of continuous contact. The test specimen is clamped onto the open face of a pressure chamber, with a retaining ring around the outer circumference of the specimen. The pressure chamber is filled with fluid test media containing a surrogate microbe. The specimen is exposed to the fluid media for a defined dwell period of time under ambient pressure. Then, chamber is pressurized, at a specified constant rate, to a maximum of 2 psi, for a defined period of time. The chamber is then allowed to revert to ambient pressure, and the specimen is exposed to the fluid media for a defined dwell period of time, to the conclusion of the test. A mesh screen may be used to support the specimen. Throughout the cycle, the reverse side of the fabric is observed for fluid media droplets, signaling failure of the barrier feature of the test fabric. If no droplets are observed thru the entire cycle, the sample will then be plated for bacteriological assay. A specimen showing liquid penetration constitutes a failure. A specimen assay identifying evidence of viable microbe that penetrates the material, even when liquid penetration is not visible, constitutes a failure. Results are reported as pass/fail.

This method was used to characterize the AAMI PB70:2012 Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities performance level, as compliant to level 4. Procedure B was used, with a mesh screen to support the sample during testing. The sample size used was n=32 and results were reported as pass/fail.

Nonwoven and nonwoven laminate materials are characterized by basis weight as opposed to thickness as basis weight is a more precise method to characterize nonwoven and nonwoven laminate performance. This is in compliance with physical specification requirements outlined in Section 3.a.1 of *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*, issued on August 1, 1993, where it states that weight per square yard or thickness, may be used as applicable.

Based on ASTM F2407-06R13, Table 2, Note B, there are no generally accepted test methods for snag or puncture resistance available at this time for nonwoven and nonwoven laminates.

The proposed product does not affect the substantial equivalence of the device, as explained below:

- **Intended use**

  The proposed Cardinal Health SmartGown™ surgical gown intended use is substantially equivalent to the predicate Cardinal Health SmartGown™ surgical gown. Intended use of proposed is the same as the predicate. The Cardinal Health SmartGown™ surgical gown is a sterile, single use, disposable medical device. Cardinal Health SmartGown™ surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Conclusion Statement

Based on the results of the biocompatibility and physical performance testing the Cardinal Health SmartGown™ surgical gowns are as safe and as effective for their intended use as the predicate device. The Cardinal Health SmartGown™ surgical gowns are substantially equivalent to the predicate device, in terms of general intended use performance testing, material composition, configuration/dimensions and safety and effectiveness.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150151

Device Name
SmartGown™ surgical gown

Indications for Use *(Describe)*

Cardinal Health SmartGown™ surgical gown surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The Cardinal Health SmartGown™ surgical gown surgical gown is a single use, disposable medical device provided sterile and non-sterile.

This submission covers 12 models of Cardinal Health SmartGown™ surgical gown, see Table 1. Each model is a multi-layer construction of a nonwoven outer layer, breathable film core and a nonwoven inner layer, and has been tested according to AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Table 1: Product Description and Catalog Number

Catalog #					
Sterile	**Non-sterile**				
Single	Bulk	Hospital	Bulk Small Qty	**Model Description**	**Model Size**
89013	N/A	N/A	N/A	SmartGown™ surgical gown, Set-in sleeve	X-Small
89005	89005N	N/A	N/A	SmartGown™ surgical gown, Set-in sleeve	Small/Medium
89015	89015N	N/A	890015N	SmartGown™ surgical gown, Set-in sleeve	Large
89045	89045N	N/A	890045N	SmartGown™ surgical gown, Set-in sleeve	X-Large
89075	89075N	K89075N	N/A	SmartGown™ surgical gown, Set-in sleeve	XX-Large
39015	39015N	K39015N	N/A	SmartGown™ surgical gown, Raglan sleeve	Large
39045	39045N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	X-Large
39049	39049N	K39049N	N/A	SmartGown™ surgical gown, Raglan sleeve	X-Large, X-Long
39075	39075N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XX-Large
39079	39079N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XX-Large, X-Long
39099	39099N	N/A	N/A	SmartGown™ surgical gown, Raglan sleeve	XXX-Large, X-Long
32474	32474N	K32474N	324740N	SmartGown™ surgical gown (specialty), Raglan sleeve	X-Large, X-Long, A-Line

The Cardinal Health SmartGown™ surgical gown is a single use, disposable medical device provided in a variety of sterile and non-sterile packaging configurations. Bulk non-sterile Cardinal Health SmartGown™ surgical gowns provided to convenience kit packers.

Non-sterile Cardinal Health SmartGown™ surgical gowns will include EO sterilization parameters on labeling as follows:

- EO Concentration: 690 mg/L
- Temperature: 130 +/- 10°F
- Exposure Time: 150 minutes
- Humidity: 50 +/- 5%
- Aeration Time: 18 hours